II. SUMMARY AND CERTIFICATION

JAN 11 2012

K111794

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Onya Dendinger
11400 73rd Avenue North
Maple Grove, MN 55369
Ph: 763-488-3410
Fax: 763-488-2051

Date Prepared: June 24, 2011

Trade Name: Reprocessed Harmonic Scalpel

Classification Name: Scalpel, Ultrasonic, Reprocessed

Classification Number: Unclassified

Product Code: NLQ

Predicate Devices:	The reprocessed harmonic scalpels are substantially equivalent to Ethicon Harmonic FOCUS™ Curved Shears (510(k) K063192).
Device Description:	SterilMed reprocessed harmonic scalpels are used in combination with a hand piece, generator, torque wrench and grip assist and are intended to be used in soft tissue surgery for simultaneous cutting and coagulation of vessels and tissue. The instrument has a scissor handle with hand control capabilities consisting of MIN and MAX buttons. The handle housing has an integrated mechanism for limiting the force that can be applied when closing the distal mechanism. The instrument has a working length of 9 cm, an active blade of 16 mm and utilizes a curved blade and clamp arm. This device allows for the cutting and coagulation of vessels up to and including 5 mm in diameter. Note: Only the harmonic scalpel is the subject of this submission, the reusable hand piece, generator, and any other related equipment are not included in the scope of this submission.
Intended Use:	The Reprocessed Harmonic FOCUS™ Scalpels (hereinafter harmonic scalpel) is indicated to be used for cutting soft tissue and providing hemostasis when control of bleeding and minimal thermal injury is desired. The instrument can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.
Functional and Safety Testing:	Representative samples of reprocessed harmonic scalpels were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F1929, ASTM F2096), and shelf life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use on beef tissue, visual inspection, fatigue testing (including repeated cycling and maximum power testing), and function testing (including system checks). Performance testing shows the Reprocessed Harmonic Scalpels to perform as intended.
Conclusion:	The reprocessed harmonic scalpels are substantially equivalent to Ethicon Harmonic FOCUS™ Curved Shears. This conclusion is based upon the devices' similarities in functional design (principles of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 11 2012

SterilMed, Inc.
% Ms. Onya Dendinger
11400 73rd Avenue North
Maple Grove, Minnesota 55369

Re: K111794
Trade/Device Name: Reprocessed Harmonic Scalpel
Regulatory Class: Unclassified
Product Code: NLQ
Dated: December 29, 2011
Received: December 30, 2011

Dear Ms. Dendinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111794

Device Name: Reprocessed Harmonic Scalpel

Indications for Use:

The Reprocessed Harmonic FOCUS™ Scalpels (hereinafter harmonic scalpel) is indicated to be used for cutting soft tissue and providing hemostasis when control of bleeding and minimal thermal injury is desired.

The instrument can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111794